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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/372,380	08/11/1999	ROMAN M. CHICZ	08191/008003	1336

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
1631	19

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/372,380	CHIEZ ET AL.	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/9/02, 10/8/02* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,17-21 and 43-92* is/are pending in the application.

4a) Of the above claim(s) *10-14,17-21,63-83 and 89-92* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,43-62 and 84-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to RCE and Amendment

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/9/02 has been entered.

The Examiner acknowledges receipt of the Amendment/Reply accompanying the RCE request filed on 5/9/02. The Amendment has been entered as Paper #14.

It is noted that page 16 of Paper #14 is missing, which appears to contain the clean version of amended claims 1-4. Applicants are requested to provide a copy of the missing page in the response to this Office action.

Election/Restriction Requirement

Applicants' election without traverse of Group I (claims 1-9, 43-62, and 84-88) in Paper #17, filed on 10/8/02 is acknowledged.

Claims 1-14, 17-21, and 43-92 are currently pending; claims 1-9, 43-62, and 84-88 are under consideration, and claims 10-14, 17-21, 63-83, and 89-92 are withdrawn from consideration as being drawn to non-elected inventions.

Applicant's arguments in Paper #14, filed 5/9/02, in response to the previous Office action, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied, and constitute the complete set presently being applied to the instant application. Rejections and/or objections not reiterated from the previous Office action are hereby withdrawn

Sequence Rules Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). Such sequences are present in Fig. 5, and elsewhere. However, this application fails to comply with the requirements of 37 CFR §1.821 through 1.825 because of the followings:

(1) Paper copy and computer readable form of a Sequence Listing, and a statement under 37 C.F.R. 1.821(f) are not provided as required by 37 CFR §1.821 through 1.825.

(2) These sequences are not followed with a sequence identifier. Applicants are reminded that it is required that SEQ ID Nos be amended into the specification at each sequence, and such sequence be on the Sequence Listing both in the paper copy and computer readable form. Applicants are reminded that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings.

Applicants are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to comply with these requirements

will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

Drawings

It is noted that a PTO-948 was mailed with Paper No. 8 on 3/23/01. Applicants were notified in the Office action, mailed 12/21/01, that the required timing for the correction of drawings had changed. Pursuant to the new rules, applicants are required to submit drawing corrections within the time period set for responding to that Office action. In Paper #14, a response to the 12/21/01 Office action, applicants assert that drawing corrections were provided with the response, however, no such drawings are filed in the case.

Applicants are required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Priority

It is noted that this application appears to claim subject matter disclosed in prior co-pending applications 60/135,728, filed 5/25/1999, and 60/096,291, filed 8/12/1998. A reference to the prior application(s) must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37

CFR 1.78(a). Also, the current status of all non-provisional parent applications referenced should be included.

Claim Rejections-35 USC § 101 and 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 43-62, and 84-88 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-9, 43-62, and 84-88 are drawn to ligand profile comprising simply a list of different polypeptide ligands. Such a ligand profile is merely a compilation or arrangement of data or facts, and is considered as nonfunctional descriptive material. "When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory" (MPEP § 2106 IV (B) (1)).

Claims 1-9, 43-62, and 84-88 are also rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a

specific, substantial, and credible utility or, in the alternative, a well-established utility.

Claims 1-9, 43-62, and 84-88 are drawn to a ligand profile which is merely a compilation or arrangement of data or facts. The specification states that such a profile can be used to compare with other profiles in identifying cellular targets useful in diagnostics, drug screening and development, etc. See page 5, lines 25-33, pages 82-84. This utility is not deemed specific because no identification of specific disease, specific target and/or specific drug is asserted. Further, the claimed profile is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, in the aforementioned utility, it takes further research to determine what disease, specific target and/or specific drug can be identified. The apparent need for such research clearly indicates that the profile is not disclosed as to a currently available or substantial utility. Similarly, the other listed and asserted utilities in the instant specification are neither substantial nor specific.

Furthermore, neither the specification as filed nor any art of record discloses or suggests any non-asserted well-established utility for the claimed ligand profile.

Claims 1-9, 43-62, and 84-88 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed ligand profile lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 8-9, 45-46, 49-51, 54-56, 59-62, and 84-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hynes et al. (FASEB J. 10, 137-147, 1996).

Hynes et al. disclose a method of isolating the binding partners of a chaperone protein, chaperonin-containing TCP-1 and establish a binding profile for the protein with its partners in testis cells. See Abstract. The TCP-1 protein is interpreted as a receptor and the binding partners as ligands. The profile includes 32 proteins/polypeptides and each is characterized based upon at least 3 different physical or chemical attributes: pI, molecular weight, database accession number for sequence listing, and spot number on the two-D gel with which the proteins are isolated. See Table I. Further, Hynes et al. also disclose the peptide mass fingerprints for spot 27. See Fig. 2.

While Hynes et al. do not explicitly disclose that this binding profile is characteristics for a given cell, they do disclose that TCP-1 and its partners are isolated from mouse testis cells. It would have been obvious to an ordinary skill in the art that the profile is characteristics of mouse testis cells.

Claims 1-9, 43-62, and 84-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hynes et al. (FASEB J. 10, 137-147, 1996) in view of Brusic et al. (Nucleic Acids Research, 1998, Vol. 26, No. 1, pages 368-371).

For claims 1-5, 8-9, 45-46, 49-51, 54-56, 59-62, and 84-88, see the rejections under 35 U.S.C. 103(a) as set forth above.

For claims 6-7, 43-44, 47-48, 52-53, and 57-58, Hynes et al. do not disclose a profile for MHC class I or II receptor. However, Hynes et al. state that the method they use to establish the profile for TCP-1, i.e. the mass spectrometry and database matching, is advantageous over traditional methods and is less laborious and fast, thus motivating using the method for establishing profiles for other proteins. See page 137, right column. Brusic et al. establish a profile for MHC class I or II including over 13000 peptide sequences. Brusic et al. state that such a profile would facilitate research on antigen processing, etc. However, the profile compiles peptides from different cell sources of different publications and Brusic et al. admit that potential errors exist. See page 370, left column. An ordinary skill in the art would have been motivated by Hynes et al. to use their strategy to establish a profile for MHC class I or II to obtain peptides from a single cell or single cell type so as to prevent the potential errors existed in Brusic et al.'s profile. Therefore, a profile of MHC class I or II would have been obvious to an ordinary skill in the art at the time the instant invention was made.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. Zhou, Ph.D.
Patent Examiner

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600